DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11430

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard Monani
Vice President
Joe Monani Fish Co., Inc.
10 Fulton Fish Market
New York, New York 10038

August 18, 2000

Ref: NYK-2000-91

Dear Mr. Monani:

We inspected your firm located at 10 Fulton Fish Market on August 1, 2000 and found that you have a serious deviation from the Seafood HAACP regulations (21 CFR Part 123). This deviation, which was previously brought to your attention, causes your fresh bluefish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood regulations through links in FDA's home page at www.fda.gov.

The deviation is as follows:

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). Your firm did not record monitoring observations for the display critical control point to control the histamine hazard listed in your HACCP plan for histamine fish, such as, bluefish, as required by 21 CFR 123.6(c)(7). Failure to maintain records documenting the monitoring of critical control points was previously brought to your attention in our letter of October 19, 1998.

Also of concern are the results of our laboratory examination of a sample of bluefish collected at your firm during the inspection of May 11 and 25, 2000. Organoleptic examination found two of nine fish examined to be decomposed. This finding may be indicative of an underlying problem with your operations, which must be corrected.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation such as, recent monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete

corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your firm. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110) You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You should send your reply to the Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer. If you have any questions regarding the content of this letter, Mr. Daurio can be reached at (718) 340-7000, ext. 5585.

Sincerely,

Brenda J. Holman
District Director